Annual report / Final report for medical devices

Ethics Committee Homolka

Full Tittle of clinical trial	
Tittle	
Protocol code Number	
CRO	
Sponsor	

Principal Investigator		**Investigators FNMH**	
Name	**Centre**	**Name**	**Centre / Phone**
Date of approval by the Ethics Committee Homolka			
The start date of the clinical trial in FNMH / global		**End date (also assumed) in FNMH / global**	

CE certification		
□ **Yes CE certificate**	□ **No CE certificate**	□ **Yes, off label use**

Information of clinical trial – study design		
□ multi-centric	□ randomized	□ retrospective
□ First-in-human	□ other:……..	

Test product / method	**Comparator**	
	□ **Yes (What):**	□ **No:**

Number of enrolled patients (signed IS) in FNMH / global	**Number of prematurely terminated patients in FNMH / global**	**Number of ongoing in FNMH / global**	**Number of completed in FNMH / global**	**Number of deaths in FNMH / global**	**Number of reported AE and AR in FNMH / global**

Adverse events(please indicate number of events in FNMH / global)		
Adverse Event – AE	**AE and AR in relation to the test product**	**Serious Adverse Event – SAE**

Brief description of the goal and course of the study. In applicable for final report risk benefit conclusion.			
Date		**Signature**	